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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Toshikazu NAKAMURA et al.

: Attorney Docket No. 2005_1807A

Serial No. 10/559,835

Filed December 6, 2005

CELL-CONTAINING PREPARATIONS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

- ☐ each U.S. Patent and U.S. Patent application publication;
- ☐ each reference previously cited in the international application PCT/_____; and/or
- ☐ each reference previously cited in prior parent application Serial No. _____.

1a. [X] This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, or

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

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TO CHARGE ANY DEFICIENCY IN THE
FEES FOR THIS PAPER TO DEPOSIT
ACCOUNT NO. 23-0975

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and thus no certification and/or fee is required.

- 1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

- (1) ☐ the certification of paragraph 2 below is provided, **or**
(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

- 1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

**the certification of paragraph 2 below is provided, and
the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.**

2. It is hereby certified

- a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or
b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.

4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☒ a full or partial English language translation submitted herewith,
 - b. ☐ a foreign patent office search report (in the English language) submitted herewith,
 - c. ☐ the concise explanation contained in the specification of the present application at page,
 - d. ☐ the concise explanation set forth in the attached English language abstract,
 - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☐ A foreign patent office search report citing one or more of the references is enclosed.
6. ☐ Statement Under 37 CFR 1.704(d)

Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart application, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Respectfully submitted,

Toshikazu NAKAMURA et al.

By Warren M. Cheek, Jr.
Warren M. Cheek, Jr.
Registration No. 33,367
Attorney for Applicants

WMC/akl
Washington, D.C. 20006-1021
Telephone (202) 721-8200
Facsimile (202) 721-8250
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FORM PTO 1449 (modified)

ATTY DOCKET NO.
2005_1807ASERIAL NO.
10/559,835U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEAPPLICANT
Toshikazu NAKAMURA et al.LIST OF REFERENCES CITED BY APPLICANT(S)
(Use several sheets if necessary)FILING DATE
December 6, 2005

GROUP

Date Submitted to PTO: February 17, 2006

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
	AC						
	AD						
	AE						

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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	AF	92/06702	4/1992	WO			
	AG	00/61156	10/2000	WO			
	AH						
	AI						

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	AJ	Kuba et al., "Organ Regeneration by HGF and Cancer Therapy by NK4", <u>Jikken Igaku</u> , Vol. 20, pp. 2143-2450, 2002. (with English translation of the Abstract and Column 5 on pages 2147-2149)
	AK	Mayumi, "Overview of Regeneration and DDS - from pharmacological viewpoint", <u>Drug Delivery System</u> , Vol. 16, pp. 10-16, 2001.
	AL	Mayumi, "The Paradigm Shift of the Drug Concept - for disease treatment by large molecular medicines", <u>Journal of Japanese Cosmetic Science Society Gakkai-Shi</u> , Vol. 26, pp. 234-238, 2002. (with English translation of the 3 rd , 9 th and 10 th paragraphs of the article)
	AM	Ikada, "Overview", <u>Protein, Nucleic Acid and Enzyme</u> , Vol. 45, pp. 2139-2141, 2000. (with its English Translation)
	AO	Yamaoka, "Molecular Designing of Biodegradable Polymer", <u>Protein, Nucleic Acid and Enzyme</u> , Vol. 45, pp. 2142-2149, 2000. (with English translation of the Abstract and Introduction on page 2142, Column 1 on page 2143, Column 4 on pages 2144-2145, and Conclusion on page 2148)
	AP	Manabe et al., "Cell-based Protein Delivery System for the Growth of Pancreatic Cancer: NK4 Gene-transduced Oral Mucosal Epithelial Cell Sheet", <u>Clinical Cancer Research</u> , Vol. 9, pp. 3158-3166, 2003.

EXAMINER

DATE CONSIDERED